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INTRAUTERINE CAUTERIZING APPARATUS AND METHODBACKGROUND OF THE INVENTION1. Field of the Invention

This invention relates to an apparatus and a method for cauterizing the tissue lining of a human body cavity, particularly the endometrium of the uterus. More specifically, the apparatus and method of the present invention ensures effective cauterization of the endometrium of a mammalian uterus without many of the disadvantages and dangerous features of known intrauterine cauterization techniques.

2. The Prior Art

The following terms as used herein have the meaning given below:

"Necrosis" means the death of cells in tissue.

"Endometrium" is that portion of the inner lining of the uterus to which an embryo normally attaches and excludes the portions of the uterine inner lining forming the cervix, to which the embryo usually does not attach.

Apparatus and methods for cauterization of the endometrium of a mammalian uterus, useful in sterilization procedures and cancer treatments, are well known. Thermal and cryogenic treatments have been utilized in such cauterization techniques and typically involve either the direct or indirect application of heat or cold to the tissue to be treated.

For example, a laser hysteroscope has been used to cauterize the endometrial layer of the uterus. This laser treatment suffers from several disadvantages. It requires the application of an intense amount of thermal energy to a relatively small area of tissue even though such a large amount of heat may not be necessary to effectively cauterize the tissue. Further, this laser treatment requires the physician

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1 to continually re-position the laser used in the treatment
2 within the uterus in order to treat the entire endometrium.
3 Such internal manipulation of a laser hysteroscope within the
4 uterus of a patient is both difficult, requiring a significant
5 level of skill to perform, and potentially dangerous.
6 Accidental puncture of the uterine or tissue wall may result
7 from manipulation of the laser scope within the uterus or body
8 cavity, and tissue layers beneath the endometrium may be burned
9 if a laser's beam is left focused on one area of tissue for too
10 long a period of time.

11 A variety of alternatives to laser treatment in
12 cauterizing the uterine endometrium are known. In U.S. Patent
13 No. 3,924,628, DroegeMueller et al. disclose a method and
14 apparatus for necrosing tissue cells that utilizes an
15 extendable bladder which is inserted in the uterus and filled
16 with a circulating fluid or gas at cryogenic temperatures
17 (referring to temperatures sufficiently low to cause cell
18 necrosis). The bladder disclosed by DroegeMueller et al. is
19 maintained in substantially continuous contact with the inner
20 surface of the uterine lining and achieves necrosis of
21 substantially all of the uterine endometrium in a single
22 treatment. DroegeMueller et al. disclose the use of liquid
23 nitrogen that vaporizes prior to introduction into the bladder,
24 thereby pressurizing the bladder to a level which ensures
25 adequate contact with the uterus. Other fluids disclosed by
26 DroegeMueller et al. as useful in their method include
27 refrigerants such as freon. DroegeMueller et al.'s method and
28 apparatus suffers from the disadvantage of employing cryogenic
29 fluids which could prove toxic to a patient in the event of
30 bladder rupture. Moreover, DroegeMueller et al.'s apparatus

1 does not allow regulating the pressure used to inflate the
2 bladder. Another disadvantage of DroegeMueller et al.'s
3 technique is that cryogenic necrosis of the endometrium occurs
4 at extremely low temperatures that pose a threat to tissue
5 layers adjacent to the uterine endometrium. DroegeMueller et
6 al. and similar cryogenic techniques also require the use of
7 expensive equipment such as compressors and insulated vessels
8 associated with the storage and transmission of refrigerants.
9 Moreover, DroegeMueller et al.'s technique may require warming
10 of the bladder in order to remove it from the body and minimize
11 tearing of the surrounding tissue which has adhered to the
12 bladder during the freezing process.

FB 13 In U.S. Patent No. 2,734,508, Kozinski discloses a
14 therapeutic apparatus for applying dry heat to body cavities
15 comprising an applicator that is introduced in the body cavity
16 while deflated and which is subsequently inflated and heated by
17 means of circulating hot air. Kozinski does not disclose an
18 applicator which conforms to the shape of a body cavity.
19 Further, given the lower heat transfer coefficients of gases as
20 compared with liquid, treatment with Kozinski's apparatus
21 should involve a long period of time in order to achieve
22 necrosis, thereby exposing the patient to additional discomfort
23 and risk. Moreover, Kozinski's apparatus does not provide for
24 measurement and regulation of internal pressures and
25 temperatures of the applicator introduced.

FB 26 U.S. Patent No. 2,077,453, issued to Albright,
27 discloses a therapeutic appliance comprising a relatively long
28 tubular applicator which is shaped and formed generally to the
29 passage into which it is to be inserted and which has
30 relatively thin elastic rubber walls that transfer heat and

1 which distend to fit irregularities of the treated areas upon
2 application of internal pressure. Albright also discloses that
3 fluids such as heated water could be utilized as a heating
4 means in his applicator. The applicator of Albright, like that
5 of Kozinski, however, suffers from the disadvantage that the
6 distension of its walls to conform to the irregularities of the
7 endometrium is limited as Albright provides an integral rubber
8 web which serves to prevent undue distension of the applicator.
9 Moreover, Albright requires that the fluid be circulated
10 throughout the apparatus. Albright also does not provide an
11 apparatus that allows regulation of temperature and pressure of
12 the fluid or other bladder inflation means.

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13 U.S. Patent No. 3,369,549, issued to Armao, discloses
14 a therapeutic device for applying heat or cold to body cavities
15 comprising a capsule probe containing a heat exchanger and a
16 flexible bladder that can be inflated to conform to a body
17 cavity. Armao does not, however, disclose a control means for
18 regulating the temperature and pressure of the flexible
19 applicator, nor does he disclose cauterizing tissue in the
20 cavity being treated.

21 Other patents that disclose the use of thermal
22 treatment of the interior lining of a body cavity include U.S.
23 Patent Nos. 2,192,768; 2,466,042; 2,777,445; and 3,369,549.

24 SUMMARY AND OBJECTS OF THE INVENTION

25 It is an object of the present invention to provide a
26 safe and efficacious method for cauterizing the tissue lining
27 of a body cavity, particularly the endometrium of a uterus.

28 It is another object of the present invention to
29 provide a relatively inexpensive and easy to replace applicator
30 heated by a nontoxic fluid that can be used to effect

1 cauterization of the uterine endometrium and which is
2 controlled by means external to the applicator.

3 It is another object of the present invention to
4 provide a non-fluid circulating apparatus for heating a fluid
5 while it is in a bladder within the uterus and for introducing
6 the fluid under pressure into the bladder so as to assure
7 substantially uniform contact of the bladder with the
8 endometrium.

9 It is still another object of the present invention
10 to provide an apparatus for regulating the temperature and
11 pressure of the fluid in the bladder while the bladder is
12 within the uterus.

13 The present invention provides a method for effecting
14 cauterization necrosis of the tissue lining of a mammalian body
15 cavity comprising the steps of inserting a distendable bladder
16 into the body cavity; inflating said distendable bladder to a
17 predetermined pressure with a fluid so that said distendable
18 bladder is in contact with substantially all of the tissue
19 lining for which necrosis is desired; heating said fluid by
20 means of a heating element positioned internal to said
21 distendable bladder; controlling the temperature and pressure
22 of said fluid by control means connected to said distendable
23 bladder; and maintaining said bladder so inflated with said
24 fluid at a temperature for a period of time sufficient to
25 effect cauterization necrosis of substantially all of the
26 tissue lining of the body cavity for which necrosis is desired.

27 The present invention also provides a method for
28 effecting cauterization necrosis of an uterine endometrium
29 comprising the steps of inserting a distendable bladder into
30 the uterus; inflating said distendable bladder to a

1 predetermined pressure with a fluid so that said distendable
2 bladder is in contact with substantially all of the
3 endometrium; heating said fluid by means of a heating element
4 positioned internal to said distendable bladder; regulating the
5 temperature and pressure of said fluid by control means
6 connected to said distendable bladder; and maintaining said
7 bladder so inflated with said fluid at a temperature for a
8 period of time sufficient to effect cauterization necrosis of
9 substantially all of the uterine endometrium.

10 The present invention further provides a method for
11 cauterizing substantially the entirety of the endometrium of a
12 mammalian uterus by application within an inflatable bladder of
13 a fluid at a pressure of 40 to 140 mmHg and preferably about 75
14 mmHg, heated to a temperature of 140~ to 215~F and preferably
15 about 210~F for a period of 4 to 12 minutes, with a preference
16 of around 6 minutes, thereby realizing substantial necrosis of
17 substantially all of the uterine endometrium without
18 significant damage to surrounding tissue.

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19 The present invention also provides an apparatus for
20 effecting necrosis of the tissue lining of a body cavity, and,
21 in particular, substantially the entirety of the endometrium of
22 a mammalian uterus comprising an applicator which comprises a
23 catheter for insertion into the uterus, said catheter having a
24 proximal end and a distal end, and a distendable bladder
25 attached to said proximal end; inflating means connected to
26 said distal end for distending said distendable bladder;
27 heating means positioned internal to said distendable bladder
28 for heating said distendable bladder; and control means for
29 regulating the distending and heating of said distendable
30 bladder.

1 The present invention provides an apparatus for
2 effecting cauterization necrosis of the tissue lining of a body
3 cavity, and in particular, substantially the entirety of the
4 endometrium of a mammalian uterine comprising means for
5 contacting the endometrium with an applicator comprising an
6 inflatable bladder mounted on a length of rigid tubing attached
7 to a length of flexible tubing; means for positioning the
8 bladder in the uterus; means for distending the inflatable
9 bladder, so as to assure substantially uniform contact with the
10 endometrium, by introduction of a fluid under pressure into the
11 applicator from a fluid source positioned external to the
12 uterus; means for heating the bladder, comprising heating the
13 fluid by a heating element positioned internal to the bladder;
14 control means positioned external to the uterus and connected
15 to the applicator by the flexible tubing and at least one wire
16 connected to the heating element for regulating the distending
17 and heating of the bladder; and means for disengaging the
18 applicator from the control means so as to separate the
19 applicator from the control means.

20 These and other objects of the present invention are
21 achieved by a method in which necrosis of the endometrium of a
22 mammalian uterus may be achieved by insertion of an applicator
23 comprising rigid and flexible tubing and a readily distendable
24 high strength bladder material into the uterus; introduction of
25 a fluid through the tubing into the distendable bladder at a
26 pressure of 40 to 140 mmHg and preferably about 75 mmHg,
27 thereby inflating the bladder so that it substantially conforms
28 to the irregularities in the shape of the endometrium; the
29 pressure of the fluid measured and regulated by means external
 to the uterus; heating the fluid to a temperature of 140~ to

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B18 1 215~F and preferably about 210~F, for a period of 4 to 12
2 minutes, with a preference of around 6 minutes, by heating
3 means positioned within the distendable bladder and regulated
4 by control means external to the applicator, thereby
5 cauterizing substantially the entirety of the uterine
6 endometrium.

DRCL 7 BRIEF DESCRIPTION OF THE DRAWINGS

P 8 Fig. 1 depicts a distendable bladder utilized in the
9 method of the present invention which has been inserted into
10 and inflated within a mammalian uterus.

11 Fig. 2 depicts placement of the distendable bladder
12 within a mammalian uterus.

13 Fig. 3 is a view of an apparatus constructed in
14 accordance with the invention that illustrates the applicator
15 connections.

16 Fig. 4 depicts a system control unit.

17 Fig. 5 is a detail view of a pressure limiting and
18 safety monitor.

19 Fig. 6A is the vented heating element shield utilized
20 in the method of the present invention.

21 Fig. 6B is a cutaway view of the vented heating
22 element shield showing the heating element and thermocouple.

23 Fig. 7 depicts a means for connecting and
24 disconnecting the applicator.

DE CL 25 DESCRIPTION OF A PREFERRED EMBODIMENT

P 26 Figure 1 shows an inflated distendable bladder 5
27 attached to rigid tubing 3 located within a human uterus 6.
28 Inflation of the distendable bladder 5 with a fluid 25 assures
29 uniform contact of the bladder with the endometrial tissue
30 layer 27 of mammalian uterus 6.

1 The rigid tubing 3 and the attached distendable
2 bladder 5 must be sufficiently small, when the distendable
3 bladder is deflated, so that it can be conveniently and safely
4 inserted into the uterus 6 through a partially dilated cervix
5 22. The rigid tubing with the deflated bladder is aligned with
6 the cervical canal after the cervix is exposed with a speculum
7 and grasped with a tenaculum. After the distendable bladder 5
8 has been inserted, the distendable bladder 5 should be inflated
9 to a pressure sufficient to ensure firm contact with the tissue
10 to be necrosed, in this case the endometrial tissue layer on
11 the interior uterine surface, but should preferably be
12 maintained at or about 40 to 140 mmHg, and preferably about 75
13 mmHg, to minimize risk of rupture of the distendable bladder 5
14 and possible internal injury to the patient.

15 Distendable bladder 5 must be capable of withstanding
16 high temperatures without rupturing, and preferably have as
17 good a heat transfer characteristic as is obtainable in such
18 materials to provide efficient heating action. A distendable
19 bladder of a heat curing rubber such as latex has been found
20 satisfactory.

21 Fluid 25 preferably should be a sterile non-toxic
22 fluid with a boiling point of at least 212°F. A five percent
23 dextrose in water solution has been found satisfactory.

24 As illustrated in Figure 2, the uninflated
25 distendable bladder 5 attached to rigid tubing 3 is inserted
26 into the vagina 21, past the cervical os 22, through the
27 cervical canal 23, for placement in the uterine cavity 20.
28 Placement may be aided by virtue of scale gradations 4 located
29 on the rigid tubing 3 to indicate the depth of insertion of the
30 bladder 5. Rigid tubing 3 is attached to a control unit 30

1 (shown in Fig. 3) via flexible tubing 10.

2 Figure 3 depicts the arrangement of control unit 30
3 and applicator end 1, comprising the distendable bladder 5,
4 rigid tubing 3 and flexible tubing 10, and the interconnection
5 of those elements. A fluid system 55 comprises that portion of
6 the invention through which the fluid 25 travels, including a
7 hypodermic barrel 14 or other fluid source (not shown),
8 flexible tubing 10, rigid tubing 3, distendable bladder 5 and
9 control unit 30. Manipulation of the hypodermic barrel 14
10 enables the operator of the system to control the amount of
11 fluid 25 in the fluid system 55, inflation and deflation of the
12 distendable bladder by adding or removing fluid, respectively,
13 and pressure of the fluid 25 in the system. Hypodermic barrel
14 also provides protection for the patient by allowing fast
15 and safe reduction of excessive pressures in the system that
16 might build up through some malfunction.

17 Manipulation of the hypodermic barrel 14 by
18 depressing a plunger 60 causes fluid 25 to be introduced
19 through 3-way stopcock 12 into the flexible tubing 10, and to
20 the rigid tubing 3. The fluid 25 emerges from rigid tubing 3
21 and into distendable bladder 5, forcing distendable bladder 5
22 to expand into contact with the endometrial tissue layer 27 of
23 the uterus 6. The fluid 25 is also directed along the flexible
24 tubing to the control unit 30 allowing measurement of the fluid
25 pressure within the bladder by well known means.

26 Each of the parts of the fluid system 55 is in fluid
27 communication providing constant fluid pressure within the
28 entire fluid system 55 and allowing measurement of the pressure
29 at the applicator end 1 via measurement of pressure of the end
30 attached to the control unit 30.

1 Control unit 30 is connected to applicator end 1 via
2 plastic sheath 15 which contains flexible tubing 10 and
3 electrical sheath 16. Flexible tubing 10 is connected to a
4 fluid joint 56 via pressure transducer 54, by well known means.
5 Using a standard luer lock connector 19, pressure transducer 54
6 and hypodermic barrel 14 are connected to flexible tubing 10
7 via a readily available 3-way stopcock 12. 3-way stopcock 12
8 may be used to isolate the hypodermic barrel 14 or other fluid
9 source from the fluid system 55 once the desired fluid pressure
10 is reached.

11 Figure 4 depicts control unit 30, consisting of fluid
12 temperature control 31, fluid pressure control 34, time control
13 38' and a power source (not shown). The control unit 30
14 includes a power switch 42 and fuse 41. Fluid temperature is
15 regulated by fluid temperature control 31 and is set by
16 temperature set/reset button 33. The temperature of fluid 25
17 in the distendable applicator 5 is shown at temperature display
18 32.

19 Fluid pressure within the fluid system 55 is
20 regulated by means of controls located on fluid pressure
21 control panel 34. The upper limit for fluid pressure is
22 controlled by high pressure set/reset button 35, with the lower
23 limit controlled by low pressure set/reset button 36. Fluid
24 pressure in mmHg is shown by LED pressure display 37. Control
25 unit 30 also has pressure indicator display 43, which upon
26 introduction of fluid 25 into the fluid system 55 provides an
27 easy to see visual display of fluid pressure within the fluid
28 system 55.

29 Time for the procedure is shown at time display 38,
30 which displays both lapsed time and time remaining for the

1 procedure. Total time for the procedure may be easily set in
2 minutes, seconds, and tenths of seconds using time set buttons
3 39 and may be cleared or reset using time clear/reset button
4 40.

5 A simplified means for determining whether the fluid
6 25 is within the preset pressure range is depicted in Figure 5,
7 which illustrates the pressure indicator display 43. The
8 pressure indicator display 43 is comprised of a low pressure
9 indicator 51, a high pressure indicator 52 and an optimum
10 pressure indicator 53. As fluid 25 is introduced into the
11 fluid system 55 by manipulation of hypodermic barrel 13, the
12 pressure indicator display 43 is successively illuminated as
13 various fluid pressures are reached. Low pressure indicator 51
14 is illuminated when fluid pressure is below the preset range.
15 High pressure indicator 52 is illuminated when fluid pressure
16 is above the preset range. Optimum pressure indicator 53 is
17 illuminated when fluid pressure is within the preset range.

18 These indicators allow the practitioner to readily
19 reach the preset pressure range by varying the amount of fluid
20 in the fluid system via manipulation of the hypodermic barrel
21 14. A separate heating element indicator 55 is also provided
22 to indicate when power is being provided to a heating element
23 44 located within the distendable applicator 5.

24 Two views of heating element 44 are shown in Figures
25 6A and 6B. Figure 6A is an external view of heating element
26 44, which comprises heating element coil shield 45 and
27 ventilation holes 46.

28 Figure 6B is a cutaway view of heating element 44,
29 wherein wire leads 49 provide power from system control unit 30
30 to heating element coil 47 causing heating element coil 47 to

1 heat the fluid 25 which comes into contact with the heating
2 element coil 47 as the fluid 25 flows through the ventilation
3 holes 46. Temperature of the fluid 25 is measured by
4 thermocouple 48 and is displayed at temperature display 32.
5 Heat element coil shield 45 prevents distendable bladder 5 from
6 contacting the heating element coil 47.

7 The applicator end 1 is designed to be easy to
8 replace as shown in Figure 7, which depicts control unit end
9 30' and applicator end 1 of the invention. Control unit end
10 30' is composed of electrical sheath 16 which is attached on
11 one end to control unit 30 and on the other end to male
12 electrical connector 24, which allows transmittal of power to
13 the heating element 44. Male electrical connector 24 is
14 readily attached or disattached to female electrical connector
15 17 on the applicator end 1.

16 Control unit end 30' is also comprised of components
17 from the fluid system 55, including flexible tubing 10 attached
18 to 3-way stopcock 12. 3-way stopcock 12 provides control over
19 the introduction and removal of fluid 25 via hypodermic barrel
20 14. The applicator end 1 is easily connected or disconnected
21 from the 3-way stopcock via a luer lock connector 19 attached
22 to pressure transducer 54.

23 The invention will now be illustrated by the
24 following example.

25 Example

26 The cauterization procedure is preceded by screening
27 against cancer of the affected region and physical condition
28 within established norms. A PAP smear and endometrial biopsy/
29 curettage must exclude cancer or precancerous lesions of the
30 uterus and cervix. If a fibroid uterus is present, an

1 ultrasound should exclude ovarian masses. The uterine cavity
2 must be 10 cm or less in length to be suitable for the small
3 distendable bladder size.

4 The patient should be post menstrual or start on
5 Danazol, or the equivalent which causes reduction in bleeding
6 and a thin endometrium, at a rate of 800 ml daily, from the 5th
7 day of the previous menstrual period until two weeks after the
8 procedure. She will undergo the procedure in the ambulatory
9 surgery unit or out-patient facility where Valium and/or
10 Demerol can be given intravenously if there is pain during the
11 heating phase of the procedure.

12 The applicator will be inserted after a bimanual
13 examination and speculum of the cervix. Dilation to 6 mm. may
14 be required which may necessitate a local 1% lidocaine block of
15 the cervix. Once in place the applicator stem protrudes from
16 the vagina and consists of an electrical connecting plug and
17 rigid tubing. Placement of the applicator may be facilitated
18 by distance markings on the rigid tubing indicating depth of
19 insertion.

20 Upon placement of the applicator it will be connected
21 to a control unit via attachment of the electrical connector
22 and flexible tubing attached to the rigid tubing to their
23 counterparts extending from the control unit.

24 Subsequent to insertion of the applicator, the
25 control unit will be powered on in order to allow the
26 practitioner to set the system constraints. The temperature of
27 the fluid in the bladder will be set at the temperature control
28 panel and can be measured via the thermocouple located within
29 the bladder. Fluid pressure constraints are set at the
30 pressure control panel, and upon inflation of the distendable

1 bladder by introduction of fluid to the fluid system by
2 depressing the plunger on the hypodermic barrel, can be easily
3 measured by looking at the pressure indicator lights located on
4 the control unit.

5 The practitioner then proceeds to inflate the
6 distendable bladder by rotating the lever on the 3-way stopcock
7 in order to access the fluid source and depressing the plunger
8 on the hypodermic barrel which may serve as the fluid source.
9 The practitioner injects the fluid into the fluid system until
10 the pressure indicator lights indicate that the fluid pressure
11 is within the pre-set constraints. At that point, the
12 practitioner manipulates the 3-way stopcock to close off access
13 to the fluid system by the fluid remaining in the hypodermic
14 barrel. Thus, the fluid is non-circulating during the heating
15 portion of the procedure, in part allowing more precise
16 measurement of fluid temperature. The volume of fluid
17 necessary to inflate the bladder will vary from 3 to 20 ml in
18 most cases in order to reach the pressure wherein the bladder
19 is substantially in contact with all of the endometrium.

20 The practitioner then turns on the heating element in
21 order to heat the fluid to a pre-set level. The heating
22 element in the bladder is connected via the plug to a 12 volt
23 system which will bring the fluid in the bladder to the level
24 of boiling as needed for each particular local, i.e. 190
25 degrees farenheit in Mexico City, and 212 degrees farenheit in
26 New York City. Once that temperature level is reached, the
27 system timer is activated to time the procedure and provide
28 automatic turn off of the heating element at the end of a pre-
29 set period.

30 Upon completion of the procedure, the 3-way stopcock

1 is again manipulated to allow the fluid to be withdrawn from
2 the fluid system causing the distendable bladder to deflate.
3 Upon deflation of the distendable bladder, the applicator may
4 be safely withdrawn from the patient. The coagulated
5 endometrium is then removed from the endometrial cavity with a
6 curette, leaving the underlying surface free to form adhesions
7 with the other opposing surfaces of the endometrial cavity.
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